

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

January 14, 2014

<u>Via E-mail</u>
Kenneth J. Hillan, M.B., Ch.B.
President and Chief Executive Officer
Achaogen, Inc.
7000 Shoreline Court, Suite 371
South San Francisco, CA 94080

Re: Achaogen, Inc.

**Draft Registration Statement on Form S-1** 

**Submitted December 18, 2013** 

CIK No. 0001301501

Dear Dr. Hillan:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

#### General

- 1. Please submit all exhibits as soon as practicable. We may have further comments upon examination of these exhibits.
- 2. Please confirm that the images included in your draft registration statement are all of the graphic, visual or photographic information you will be including. If you intend to use any additional images, please provide us proofs of such materials. Please note that we may have comments regarding this material.
- 3. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications. Similarly, please

supplementally provide us with any research reports about you that are published or distributed in reliance upon Section 2(a)(3) of the Securities Act of 1933 added by Section 105(a) of the Jumpstart Our Business Startups Act by any broker or dealer that is participating or will participate in your offering.

#### Prospectus Summary, page 1

- 4. Please define the following scientific terms to provide a reasonable investor with an understanding of such terms:
  - "gram-negative;"
  - "Enterobacteriaceae;"
  - "carbapenem-resistant;"
  - "extended-spectrum beta-lactamase producing Enterobacteriaceae;"
  - "semi-synthetic aminoglycoside;"
  - "in vitro;"
  - "in vivo;"
  - "levofloxacin;" and
  - "antipseudomonal."

#### Risk Factors, page 11

"We are substantially dependent on the success of our lead product candidate...," page 12

5. We note your discussion here and elsewhere in the registration statement of prior clinical trials of plazomicin. Please clarify here and throughout the registration statement where you refer to prior clinical trials of plazomicin that these clinical trials did not test the indication for which you are currently seeking an NDA, which is for use against MDR Enterobacteriacaea, or CRE.

"We are highly dependent on the services of our Chief Executive Officer...," page 28

6. Please disclose any difficulties you have experienced attracting or retaining qualified management or experienced personnel in the past.

"A variety of risks associated with international operations...," page 31

7. We note that you have a "sole source supplier for sisomicin, a key raw material for the production of plazomicin." Please expand your disclosure to state that you do not have an agreement with the Chinese manufacturer of sisomicin.

#### Use of Proceeds, page 55

8. We note your disclosure that you will use a portion of the proceeds to support your planned registration program for plazomicin. Please revise this language to state, if true, that the proceeds of the BARDA contract and the offering are expected to be sufficient to fund development of plazomicin to the reporting of topline data in 2017 but not through the filing of an NDA or approval.

Management's Discussion and Analysis of Financial Condition and Results of Operations, page 65

Financial Overview and Results of Operations, page 73

#### Contract Revenue, page 74

9. We note your disclosure that you modified the BARDA contract in November of 2013 and expect that costs incurred for services to be provided under the contract will exceed the revenue from the contract. Please state how much of the \$103.8 million value of the contract is still to be received upon delivery of services. Please also quantify the extent to which you expect costs to exceed the potential additional revenue that may be realized.

# Comparison of Nine Months Ended September 30, 2012 and 2013, page 76 Research and Development Expenses, page 76

10. While you state here that your Phase 2 clinical trial of plazomicin was completed during the first half of 2012, and throughout the filing that you will commence Phase 3 during the first quarter of 2014, it appears that you continued to incur expenses for external research and development for plazomicin subsequent to the first half of 2012. Please revise your discussion herein and in the comparison of fiscal years ended December 31, 2011 and 2012 to separately disclose the amount of these expenses incurred after completing the Phase 2 clinical trial each period during the nine months ended September 2012, fiscal year ended December 31, 2012 and the nine months ended September 30, 2013. In your discussion, please describe the nature of the activities that were conducted and types of these expenses incurred related to the post Phase 2 clinical trial activities.

#### Business, page 84

11. Please disclose any INDs that you have filed with the FDA. Please also state when they were filed, who filed them, and what they cover.

#### <u>Plazomicin, page 89</u> Plazomicin Development Program, page 92

12. On page 93 please provide the long form of the abbreviated terms "QT" and "TQT" and explain their meaning.

# <u>Plazomicin Clinical Data Are Supportive of Further Trials of Plazomicin in Patients with CRE,</u> page 100

13. For each clinical trial you have conducted for plazomicin, please list any adverse event experienced.

#### Government Contracts, page 105 BARDA, page 105

- 14. We note your disclosure that the activities under Option 3 of the BARDA agreement include certain non-clinical studies necessary to support an NDA, an open-label safety study and a non-clinical biodefense study. It is unclear whether you have discussed the additional non-clinical study necessary to support an NDA in your discussion of the development of plazomicin. If not, please identify and describe this non-clinical study necessary to support an NDA in your discussion of the development of plazomicin. Please also discuss the open-label safety study if this will also be required to support an NDA.
- 15. Please disclose the terms of the November 2013 amendment and explain why and how your costs will rise as a result of the amendment. Please also quantify the anticipated increase in your cost of providing services under the BARDA agreement.

## <u>Intellectual Property, page 109</u> <u>Plazomicin (Aminoglycoside), page 109</u>

16. We note that you have not disclosed patents licensed from Isis regarding the manufacturing or use of Plazomicin. To the extent these patents are material, please provide similar information for them as you have provided for the patents related to Plazomicin that you own.

#### Executive and Director Compensation, page 132

17. Please update the Executive Compensation section to include 2013 executive compensation information. You should retain the 2012 information in the Summary Compensation Table.

### <u>Certain Relationships and Related Party Transactions, page 145</u> Investor Rights Agreement, page 147

18. If the Investor Rights Agreement will survive your initial public offering, please file this agreement as an exhibit to the registration statement. In the alternative, please state that the agreement will not survive your initial public offering.

### Shares Eligible for Future Sale, page 156 Lock-Up Agreements, page 156

19. When available, please file a form of the lock-up agreement as an exhibit to your registration statement.

#### General

If you intend to respond to these comments with an amended draft registration statement, please submit it and any associated correspondence in accordance with the guidance we provide in the Division's October 11, 2012 announcement on the SEC website at http://www.sec.gov/divisions/corpfin/cfannouncements/drsfilingprocedures101512.htm.

Please keep in mind that we may publicly post filing review correspondence in accordance with our December 1, 2011 policy (http://www.sec.gov/divisions/corpfin/cfannouncements/edgarcorrespondence.htm). If you intend to use Rule 83 (17 CFR 200.83) to request confidential treatment of information in the correspondence you submit on EDGAR, please properly mark that information in each of your confidential submissions to us so we do not repeat or refer to that information in our comment letters to you.

You may contact Keira Nakada at (202) 551-3659 or James Rosenberg at (202) 551-3679 if you have questions regarding comments on the financial statements and related matters. Please contact Christina De Rosa at (202) 551-3577 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Jeffrey P. Riedler

Jeffrey P. Riedler Assistant Director

cc: Via E-mail
Mark V. Roeder
Latham & Watkins LLP
140 Scott Drive
Menlo Park, CA 94025